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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,989	02/05/2004	Paul A. Iaizzo	P0008965.00/LG10126	5392
27581	7590	06/11/2010		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER BERTRAM, ERIC D	
			ART UNIT 3766	PAPER NUMBER
			NOTIFICATION DATE 06/11/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/772,989	Applicant(s) IAIZZO ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,7,11,12,18,20,21,23,24,26-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,4,7,11 and 12 is/are allowed.
- 6) ☒ Claim(s) 18,20,21,23,24,26-28 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/1/2010 has been entered.

Response to Arguments

2. Applicant's arguments filed 4/1/2010 regarding claims 18, 20, 21, 23, 24, 27, 28, 30-35 have been fully considered but they are not persuasive. Applicant argues that Lampadius does not disclose the amendments made to claim 18. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

3. In this case, the rejection would still be valid because the combination of Lampadius and Starksen teach the advancement of the lead of Lampadius through a catheter lumen to the treatment site (see par. 17 of the previous office action and below). In order to advance the lead of Lampadius through a catheter as taught by Starksen, the guard would obviously have a smaller diameter than the inner diameter of the catheter. Since the applicant has not addressed the combination of Lampadius and

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Starksen, and since the Examiner still believes the combination to be appropriate, the 35 USC 103(a) rejections of claims 18, 20, 21, 23, 24, 27, 28, 30-35 are still considered proper.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 18, 20, 23, 24, 27, 30-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius in view of Starksen.

8. Regarding claims 18, 27, 30 and 32, Lampadius discloses a medical lead as shown in figures 1-3. The figures all show the distal end of the lead body 23, which includes a glue segment 67 disposed around a tip electrode 65. The glue segment comprises a tissue adhesive encapsulated in a biocompatible capsule (i.e., "plastic ampul") that is formulated to rupture when said lead is urged against a treatment site, liberating the tissue adhesive, and affixing the lead body to the treatment site (see the second to last paragraph in the translation). Furthermore, the distal end 81 is considered a guard for the glue segment, since it extends out past the sides of the glue segment, much like the guard 18 shown in figure 1 of the applicant's specification, and also extends out past the distal end of the lead body, and would prevent the glue segment from contacting a wall of a catheter lumen as the lead is advanced therethrough. As such, the guard has a larger diameter than the lead body of the lead.

9. However, while Lampadius does disclose the use of a catheter 23,79 for insertion of the lead, Lampadius is silent as to the guard having a smaller diameter than a catheter so that the lead may be implanted by advancing the lead through the catheter. Attention is directed to the secondary reference of Starksen, which discloses a guide catheter 10 with a lumen wide enough to accommodate cardiac leads (Col. 4, lines 5-12). After placing the catheter in the proper location, and utilizing balloon 18 to protect the heart tissue (Col. 4, lines 29-40), the lead will be advanced through the catheter to a treatment site (Col. 5, lines 58-65). Therefore, it would have been obvious to one of

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ordinary skill in the art at the time of the applicant's invention to modify Lampadius to utilize a catheter as described in Starksen, since this is a known apparatus for the introduction of leads in the heart and would have allowed an electrical lead to be properly implanted at a treatment site. Furthermore, it would be obvious that in order to achieve this, the guard would have to have a smaller diameter than the inner diameter of the catheter.

10. Regarding claim 20, Lampadius discloses the adhesive may be a 2-butyl cyanoacrylate (i.e., "Butyl-2-zyanoakrylat").

11. Regarding claims 23 and 24, Lampadius discloses the glue segment is torus-shaped, which is both annular and tubular.

12. Regarding claims 26 and 31, Lampadius discloses that the adhesive could be delivered through a lumen in the lead and forced through ports 17 (see figure 1). As the adhesive is forced through the ports, two dots will inherently form.

13. Regarding claim 35, an implantable medical device must inherently be connected to the lead in order to apply the electrical energy.

14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Munch et al. (US 6,463,335, hereinafter Munch).

While Lampadius discloses the applicant's basic invention, including a tissue adhesive for securing a medical lead to the heart, Lampadius is silent as to using a fibrin glue as the tissue adhesive. Attention is directed to the secondary reference of Munch, which discloses a electrode secured to the heart by using a fibrin glue (Col. 20, lines 1-32).

Therefore, it would have been obvious to one of ordinary skill in the art to substitute

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fibrin glue for the n-butyl cyanoacrylate of Lampadius since both are known biocompatible tissue adhesives, and both would work equally well in securing a lead to the heart.

15. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Williams et al. (US 6,516,230, hereinafter Williams). While Lampadius discloses the applicant's basic invention, including a tip electrode for contacting the heart, Lampadius is silent as to using a tip electrode shaped as a helix coil. Attention is directed to the secondary reference of Williams, which discloses a tip electrode 16 in the shape of a helix coil (Col. 3, lines 5-6). Therefore, it would have been obvious to one of ordinary skill in the art to substitute the helix electrode of Williams for the tip electrode of Lampadius since both are known tip electrode configurations, and the helix electrode has the benefit of providing additional anchoring at the treatment site.

16. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Sigg et al. (US 6,931,286, hereinafter Sigg). Lampadius, as modified above, discloses the applicant's basic inventive concept with the exception of the catheter including mapping electrodes. Column 5, lines 20-30 of Sigg describes the use of a mapping catheter during the implantation of electrical leads. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sigg et al. to modify the system of Lampadius by adding a lumen in the lead in order to apply the tissue adhesive to the application

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site and to also include mapping electrodes in order to locate a desirable application site.

17. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampadius and Starksen in view of Igo et al (US 6,666,844, hereinafter Igo).

Lampadius, as modified above, disclose the applicant's basic inventive concept with the exception of the catheter having a suction capacity. Column 6, line 65 of Igo discloses a passage 120 in the catheter that is to supply a vacuum to withdraw fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Igo to modify the system of Lampadius, as modified, by adapting the catheter to apply suction to a tissue site in order to remove excess moisture from the site.

Allowable Subject Matter

18. Claims 3, 4, 7, 11 and 12 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is (571)272-3446. The examiner can normally be reached on Monday-Thursday from 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric D. Bertram/
Examiner, Art Unit 3766